



United States Patent and Trademark Office

[Home](#) [Site Index](#) [Search](#) [FAQ](#) [Glossary](#) [Guides](#) [Contacts](#) [eBusiness](#) [eBiz alerts](#) [News](#) [Help](#)**Trademarks > Trademark Electronic Search System(Tess)**

TESS was last updated on Sat Nov 18 04:18:56 EST 2006

[TESS HOME](#)[NEW USER](#)[STRUCTURED](#)[FREE FORM](#)[BROWSE DICT](#)[SEARCH OG](#)[BOTTOM](#)[HELP](#)[Logout](#)

Please logout when you are done to release system resources allocated for you.

Record 1 out of 1[TARR Status](#)[ASSIGN Status](#)[TDR](#)[TTAB Status](#)

(Use the "Back" button of the Internet

Browser to return to TESS)**Typed Drawing****Word Mark** NYSTATIN VT**Goods and Services** (ABANDONED) IC 005. US 006 018 044 046 051 052. G & S: pharmaceutical preparation, namely, vaginal antifungal agent**Mark Drawing Code** (1) TYPED DRAWING**Design Search Code****Serial Number** 76090875**Filing Date** July 17, 2000**Current Filing Basis** 1B**Original Filing Basis** 1B**Owner** (APPLICANT) Odyssey Pharmaceuticals, Inc. CORPORATION NEW JERSEY 72 DeForest Ave. East Hanover NEW JERSEY 07936**Assignment Recorded** ASSIGNMENT RECORDED**Attorney of Record** Margaret F. Goldstein**Type of Mark** TRADEMARK**Register** PRINCIPAL**Live/Dead Indicator** DEAD**Abandonment Date** August 16, 2001[TESS HOME](#)[NEW USER](#)[STRUCTURED](#)[FREE FORM](#)[BROWSE DICT](#)[SEARCH OG](#)[TOP](#)[HELP](#)[HOME](#) | [SITE INDEX](#) | [SEARCH](#) | [eBUSINESS](#) | [HELP](#) | [PRIVACY POLICY](#)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Pamela M. Drake et al.
Application No. : 10/763,570
Filed : January 23, 2004
Confirmation No. : 4880
For : COMPOSITIONS AND METHODS FOR RESTORING
BACTERIAL FLORA

Examiner : Lora E. Barnhart
Art Unit : 1651
Docket No. : 340082.401
Date : _____

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF PAMELA M DRAKE
PURSUANT TO 37 CFR § 1.132

Commissioner for Patents:

I, **Pamela M. Drake**, declare as follows:

1. I, **Pamela M. Drake**, am familiar with the subject matter disclosed and claimed in U.S. Patent Application No. 10/763,570, filed January 23, 2004, and titled "COMPOSITIONS AND METHODS FOR RESTORING BACTERIAL FLORA" ("the '570 Application").
2. I am **President of Flora Technology, Inc.**, located in **Aberdeen, Washington, United States**.
3. My educational and professional background includes is attached.

4. I have reviewed the Office Action dated August 31, 2006, including the Examiner's rejections and cited references.
5. I am familiar with the contents of the '570 Application.
6. Routine antibiotic use contributes to significant health problems related to the disruption of intestinal flora. Examples of some of the significant health problems associated with routine antibiotic use include the growth of opportunistic, anti-microbial resistant infections, such as Methicillin Resistant *Staphylococcus aureus* (MRSA), *E. coli*, *Clostridium difficile*, and fungal infections. Medical Practitioners have seen an increase in cases of resistant infections and other complications following antibiotic use.
7. The cost of treating patients with antibiotics often increases because the disruption of the gut flora may create additional complications requiring continual medical intervention. The solution lies in re-establishing healthy intestinal flora, which may be accomplished by administering a probiotic alongside the anti-microbial.
8. Probiotics are live, beneficial microbes that protect their host and prevent disease. The present standard of care relating to antibiotic use does not include the concurrent use of probiotics. Instead, probiotics are usually provided after an opportunistic infection has already arisen.
9. Probiotics, if suggested or prescribed by a physician, are presently available primarily as a separate purchase.
10. Most insurance companies do *not* cover separate probiotic purchases. Patients must therefore pay for probiotic supplements separately, and at the patient's own expense.
11. There exists both a critical and a long-felt need for a product that effectively combines both anti-microbial and probiotic treatments in a single kit, and which may be sold to the patient as a single prescription.
12. I am familiar with the contents of U.S. Patent No. 6,645,506 ("the 'Farmer' patent").

13. The "Farmer" patent merely discloses the use of *topical* probiotic compositions, which are not useful for treating anti-microbial disruptions of the intestinal flora.
14. There is a critical and long-felt need for an anti-microbial/probiotic kit that is not exclusively topical, and which may be used to treat disruptions of the intestinal flora.
15. The enclosed letters offer evidence that medical practitioners indicate that their patients would benefit from a kit that combines both a probiotic and anti-microbial in a single prescription, and that they would routinely prescribe such a kit if it were available.
16. The enclosed letters were written by primary care medical practitioners in support of anti-microbial/probiotic kits that are presently under development by Flora Technologies, and include letters from Roy Ozanne, M.D., H.M.D., Colette M. Kato, D.O., Patrician Sylwester, M.D., Karolina Wilczynaka-Oberc, M.D., Patrick Litster, M.P.A.S., PA-C, Ann Tosomeen, M.D., Maribeth T. Duffy, M.D., and Pamela J. Baxter, PA-C, R.T.R.M.

I hereby declare that all statements made herein are, to my own knowledge, true and that all statements made on information or belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the captioned patent application or any patent issued therefrom.

Date

Name

Roy Ozanne, M.D.

5277Country Lane
Langley, WA 98260

Phone: 360-321-4116
Fax: 360-321-4116
Email: royozone@comcast.net

January 7, 2007

One of the world's most significant health problems is the growth of opportunistic, anti-microbial resistant infections such as MRSA, e-coli, clostridium difficile and fungi that too often follow routine anti-microbial use.

This problem, and many others, stem largely from the disruption of healthy intestinal flora by anti-microbial medication. The solution lies in re-establishing healthy intestinal flora. Probiotic therapy is shown to be extremely useful in this regard and should be given whenever anti-microbials are prescribed.

Currently, this is not the standard of medical practice. Probiotics are usually tried after an opportunistic infection has already arisen and the patient is seeking relief from other practitioners than the original prescriber of the anti-microbial. Also, even if the probiotics were suggested earlier, the patient's insurance company usually only covers the antimicrobial, not the probiotic and so the probiotic is too often not taken and opportunistic infections arise.

By not prescribing an effective probiotic with every dose of anti-microbial medication, we are missing a great opportunity to prevent subsequent opportunistic infections with all the extra morbidity, cost and bad will toward the original anti-microbial medication and practitioner that prescribed it. When patients take an effective probiotic along with their anti-microbial medication, their intestinal flora and future health is protected and their relationship with their primary practitioner is preserved.

A great way to increase the concomitant use of probiotics with anti-microbials is to supply them through a single prescription. I have become aware of a patent-pending product that includes both a probiotic and an antifungal in one kit. Such a kit would greatly benefit patients by making the probiotic easily available and affordable by coming as a prescription. I am looking forward to this kit becoming available.

Sincerely,



Roy Ozanne, M.D., F.M.D.

Colette M. Kato, D.O.
1220 Basich Blvd. Suite A
Aberdeen, WA 98520

January 9, 2007

To Whom It May Concern:

In the ever-increasing battle against MRSA, e-coli, clostridium difficile and fungal invasions following antibiotic usage and other forms of medical intervention, we are clearly in a health crisis!

I am seeing more bacterial resistance than ever before. MRSA is becoming a household name, rather than hospital only. Clearly acute infections are becoming chronic infections and not necessarily responding to antibiotics. I have recommended probiotics and prescribed antifungals, however, the problem at hand is that the patient is too inconvenienced to purchase the probiotic and the patient's insurance will only cover the prescribed antifungal. This scenario at times makes it cost prohibitive for the patient to use both items. Therefore they miss the advantage of attempting to support their gut flora and this in turn leaves them open to the many health invasions we are so aware of. It has been my experience that the actual cost of treating my patients may have increased greatly because this disruption of the gut flora often creates additional complications requiring continual medical intervention.

I have become aware of a patent-pending product that includes both a probiotic and an antifungal in one kit. I would like to say that such a kit would greatly benefit my patients by making both items easily available and affordable by becoming a prescription. It may be possible that this kit could eliminate the need for further medical interventions by supplying an anti-fungal and friendly bacteria as one affordable source. I would be more inclined to routinely prescribe such a kit if it were available.

Sincerely,



Colette M. Kato, D.O.

Jan 24 07 08:42p

Jeffrey W. Nejedly

360-570-8034

p.2

To Whom It May Concern,**1/24/07**

I am a physician practicing Urgent Care in Washington State. I write for antibiotics every day in my clinical practice. I am very much aware of the risks of these antibiotics to my patients. Studies have proven that use of antibiotics, while necessary in many patients, leads to overgrowth of pathologic bacteria and yeast, such as Clostridium difficile, MRSA, and Candida. Many of these pathogens can be life threatening.

I have recently become aware of a product that is in the patenting process which interests me very much. This product combines probiotics with Nystatin, a very safe antifungal. It would be prescribed orally to prevent yeast and pathologic bacteria overgrowth while patients are taking antibiotics. Many of my patients have been made aware of the benefits of probiotics to prevent these risks and understand their benefits, and yet do not purchase them, despite my educational intervention, because they are not carried at their pharmacy and are not covered by their insurance.

I would definitely prescribe this medicine as soon as it is available.

Sincerely,



Patricia Sylwester M.D.
Pacific Walk-In Clinic
3928 Pacific Ave
Lacey, WA 98503
(360) 455-1350

To Whom It May Concern,

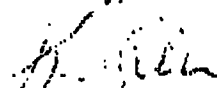
1/24/07

I am a Family Medicine Physician in Washington State. Every day I prescribe antibiotics in my clinical practice. I am very much aware of the risks of these antibiotics to my patients. Studies have proven that use of antibiotics, while necessary in many patients, leads to overgrowth of pathologic bacteria and yeast, such as Clostridium difficile, MRSA, and Candida. Many of these pathogens can be life threatening.

I have recently become aware of a product that is in the patenting process which interests me very much. This product combines probiotics with Nystatin, a very safe antifungal. It would be prescribed orally to prevent yeast and pathologic bacteria overgrowth while patients are taking antibiotics. Many of my patients have been made aware of the benefits of probiotics to prevent these risks and understand their benefits, and yet do not purchase them, despite my educational intervention, because they are not carried at their pharmacy and are not covered by their insurance.

I would definitely prescribe this medicine as soon as it is available.

Sincerely,



Karolina Wilczynska-Oberc
Tumwater Family Practice
150 Dennis St. S.W.
Tumwater, WA 98501-5469
(360) 754-6367
(360) 7548-429 FAX

1/9/2007


To Whom It May Concern:

In the ever-increasing battle against MRSA, e-coli, clostridium difficile and fungal invasions following antibiotic usage and other forms of medical intervention, we are clearly in a health crisis!

I currently work in a small community hospital Emergency department. We see more than 45,000 patients annually, and a day does not go by that I do not treat a patient with either MRSA or suspect C-Diff, from antibiotic related diarrhea. I am seeing more bacterial resistance than ever before. MRSA is becoming a household name, and not just for the hospital any longer! Clearly acute infections are becoming chronic infections and not necessarily responding to antibiotics. I have recommended probiotics and prescribed antifungals, however, the problem at hand is that the patient is too inconvenienced to purchase the probiotic and the patient's insurance (be it private, Medicare or Medicaid) will only cover the prescribed antifungal. This scenario at times makes it cost prohibitive for the patient to use both items. Therefore they miss the advantage of attempting to support their gut flora and this in turn leaves them open to the many health invasions we are so aware of. It has been my experience that the actual cost of treating my patients may have increased greatly because this disruption of the gut flora often creates additional complications requiring continual medical intervention.

I have become aware of a patent-pending product that includes both a probiotic and an antifungal in one kit. I would like to say that such a kit would greatly benefit my patients by making both items easily available and affordable by becoming a prescription. It may be possible that this kit could eliminate the need for further medical interventions by supplying anti-fungal and friendly bacteria as one affordable source. I would be more inclined to routinely prescribe such a kit if it were available.

Thank You


Patrick Litster, MPAS, PA-C

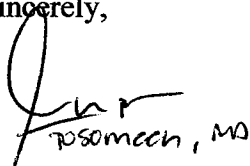
To Whom It May Concern:

In the ever-increasing battle against MRSA, e-coli, clostridium difficile and fungal invasions following antibiotic usage and other forms of medical intervention, we are clearly in a health crisis!

I am seeing more bacterial resistance than ever before. MRSA is becoming a household name, rather than hospital only. Clearly acute infections are becoming chronic infections and not necessarily responding to antibiotics. I have recommended probiotics and prescribed antifungals, however, the problem at hand is that the patient is too inconvenienced to purchase the probiotic and the patient's insurance will only cover the prescribed antifungal. This scenario at times makes it cost prohibitive for the patient to use both items. Therefore they miss the advantage of attempting to support their gut flora and this in turn leaves them open to the many health invasions we are so aware of. It has been my experience that the actual cost of treating my patients may have increased greatly because this disruption of the gut flora often creates additional complications requiring continual medical intervention.

I have become aware of a patent-pending product that includes both a probiotic and an antifungal in one kit. I would like to say that such a kit would greatly benefit my patients by making both items easily available and affordable by becoming a prescription. It may be possible that this kit could eliminate the need for further medical interventions by supplying an anti-fungal and friendly bacteria as one affordable source. I would be more inclined to routinely prescribe such a kit if it were available.

Sincerely,



J. R. Roseman, MD

January 4th, 2007

Shoalwater Bay Wellness Center

2373 Tokeland Road Bldg. E

Po Box 500

Tokeland, WA 98590

Phone: 360-267-0119 Fax: 360-267-0417

Ann Tosomeen, M.D. Pam Baxter P.A.-C Maribeth Duffy, M.D. Jeanne Boudrieau, ARNP

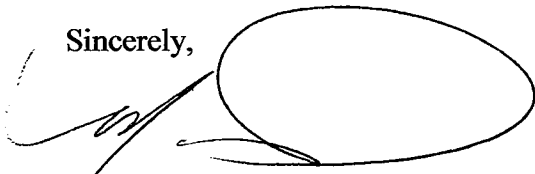
To Whom It May Concern:

Due to the rise in incidence of MRSA, E-coli, Clostridium difficile and fungal infections associated with antibiotic usage and other necessary medical interventions, I am writing this letter. We are clearly in a health crisis!

I am seeing more bacterial resistance than ever before. MRSA is becoming a household name, rather than hospital only. Acute infections are becoming chronic infections and are not always responding to antibiotics. I have recommended probiotics for my patients and of course anti-fungals when clinically appropriate, however, more often than not the patient does not purchase the probiotic due to the inconvenience of a second stop (after the pharmacy) to a health food store or grocery store, and the fact that probiotics are not covered by the patient's insurance. This scenario at times makes it cost prohibitive for the patient to follow my recommendations. They miss the advantage of attempting to support their gut flora and this in turn leaves them open to the many of the above mentioned opportunistic infections. It has been my experience that the actual cost of treating most patients increases greatly because of the disruption of the gut flora creating additional complications requiring continual medical intervention.

I have become aware of a patent-pending product that includes both a probiotic and an anti-fungal in one kit. I would like to say that such a kit would greatly benefit my patients by making both items easily available and affordable by becoming a prescription. It may be possible that this kit could eliminate the need for further medical interventions by supplying an anti-fungal and friendly bacteria as one affordable source. I would be more inclined to routinely prescribe such a kit if it were available.

Sincerely,

A handwritten signature in black ink, appearing to read 'Maribeth T. Duffy', with a large, loopy flourish extending from the end of the signature.

Maribeth T. Duffy

1/7/07

To Whom It May Concern:

In the past decade, medical practitioners have seen an alarming increase in cases of resistant infections and other complications following antibiotic usage. MRSA, once thought to be a hospital-borne infection only, is now a common infection in the population I serve. There is mounting evidence that even with appropriate antibiotic usage; we are inadvertently contributing to preventable serious complications and inflation of the cost of medical care in the United States.

It is common practice for me to need to prescribe systemic antifungals for secondary fungal infection after a patient has finished a course of antibiotics. It is also common for me to see significant GI problems after antibiotics have essentially stripped a patient of their normal GI flora. Thus I often recommend a course of probiotics to my patients who've needed frequent antibiotics.

My clinic serves a medically complex population, where approximately 50% of our patients suffer from multiple significant conditions. Secondary infections of MRSA, clostridium difficile, or invasive fungal infections can be devastating and potentially life-threatening in this type of patient. Our complex patients who are on multiple medications and a limited fixed income can't afford to pay out of pocket for probiotics as a preventative measure.

I have been informed of a patent-pending product that includes both a probiotic and an antifungal in one kit. I feel that such a kit would greatly benefit my patients by making both items easily available and affordable secondary to being in prescription form. I would definitely be inclined to routinely prescribe such a product if it were available.

Sincerely,

Pamela J. Baxter, PA-C, RTRM
Women's Health Program Manager
Shoalwater Bay Wellness Center
PO Box 500, Tokeland, WA. 98590
360-267-0119